PROPOSED RULE MAKING

CR-102 (June 2004)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

Agency: Department of Health - Board of Pharmacy

☒ **Preproposal Statement of Inquiry was filed as WSR** 03-18-117 ; **or**
☐ **Expedited Rule Making--Proposed notice was filed as WSR** _____ ; **or**
☐ **Proposal is exempt under RCW 34.05.310(4).**

☒ **Original Notice**
☐ **Supplemental Notice to WSR** _____
☐ **Continuance of WSR** _____

Title of rule and other identifying information: (Describe Subject) WAC 246-872 Automated Drug Distribution Devices. The proposed rule will create a new chapter in WAC 246 and will adopt uniform standards for the use of automated drug distribution devices for those facilities that choose to use them. In addition, the proposed rules will include current Board of Pharmacy requirements for drug storage, security, and accountability in WAC 246-873-070 and -080. It will recognize the automated drug distribution device as an appropriate storage site for controlled substances.

Hearing location(s): Department of Health, 310 Israel Road, Room 152-153 PPE, Tumwater, WA 98501

Date: July 20, 2006 Time: 10:00 a.m.

Date of intended adoption: July 20, 2006
(Note: This is **NOT** the effective date)

Submit written comments to:
Name: Tim Fuller
Address: PO Box 47863
Olympia WA 98502-7863
e-mail www.doh.wa.gov/policyreview/
fax (360)586-4359 by (date) July 19, 2006

Assistance for persons with disabilities: Contact
Doreen Beebe by July 5, 2006
TTY (800) 833-6388 or ( ) 711

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The proposed rule will create new chapter, WAC 246-872, regarding Automated Drug Distribution Devices. It will set standards for the use of these devices for hospitals and healthcare facilities, which the current rules do not. In addition, they will provide standards that will improve medication safety, appropriate access to medications, and accountability, particularly for controlled substances. The current rule WAC 246-869-120, mechanical devices in hospitals, applies to devices that are not available. For the few devices in use, the mechanical device rule will remain in place.

Reasons supporting proposal: Hospitals and other healthcare facilities have purchased automated drug distribution devices to store and distribute medications. For public health and safety, the Board of Pharmacy establishes the minimum standards automated devices meet the standards for drug storage, security, distribution, and accountability.

Statutory authority for adoption: 18.64.005 RCW

Statute being implemented: 18.64.005 RCW

Is rule necessary because of a:

Federal Law?	☐ Yes	☒ No
Federal Court Decision?	☐ Yes	☒ No
State Court Decision?	☐ Yes	☒ No

If yes, CITATION:

DATE 05/02/06

NAME (type or print) Steven M. Saxe

SIGNATURE

TITLE Executive Director

CODE REVISER USE ONLY

CODE REVISER'S OFFICE
STATE OF WASHINGTON
FILED

MAY 3 2006

TIME 1000 AM PM

WSR 06-10-082

(COMPLETE REVERSE SIDE)

(COMPLETE REVERSE SIDE)

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:
None.

Name of proponent: (person or organization) Department of Health - Board of Pharmacy

☐ Private
☐ Public
☒ Governmental

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting.....	Tim S. Fuller	PO Box 47863	(360)**236-4825**
Implementation....	Steven M. Saxe	PO Box 47863	(360) **236-4825**
Enforcement.....	Steven M. Saxe	PO Box 47863	(360) **236-4825**

Has a small business economic impact statement been prepared under chapter 19.85 RCW?

☒ Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:
Name: Tim Fuller
Address: PO Box 27863
Olympia, WA. 98502-7863

phone (360) 236-4827
fax (360)586-4359
e-mail timothy.fuller@doh.wa.gov

☐ No. Explain why no statement was prepared.

Is a cost-benefit analysis required under RCW 34.05.328?

☒ Yes A preliminary cost-benefit analysis may be obtained by contacting:
Name: Tim Fuller
Address: PO Box 27863
Olympia, WA. 98502-7863

phone (360) 236-4827
fax (360)586-4359
e-mail timothy.fuller@doh.wa.gov

☐ No: Please explain:

Chapter 246-872 WAC

AUTOMATED DRUG DISTRIBUTION DEVICES

NEW SECTION

WAC 246-872-010 Purpose. The purpose of this chapter is to better ensure that licensed pharmacies and health care facilities that choose to use automated drug distribution devices to distribute medications both in a secure manner to protect public health and safety and in a manner that provides access to medications for quality care. The chapter defines appropriate medication security, accountability, and device performance as well as patient confidentially. It specifies standards of care and provides guidance on how to meet those standards and required approval by the board of pharmacy.

NEW SECTION

WAC 246-872-020 What definitions do I need to know to understand these rules? (1) "Automated drug distribution devices" means automated equipment used for remote storage and distribution of medication for use in patient care. The system is supported by an electronic data base.

(2) "Information access" means entry into a recordkeeping component of the automated drug distribution device, by electronic or other means, to add, update, or retrieve any patient record, medication record, or other data.

(3) "Medication access" means the physical entry into any component of the automated drug distribution devices to stock, inventory, remove medications, or repair the device.

NEW SECTION

WAC 246-872-030 What are the pharmacy's responsibilities? Each facility using drug distribution devices must designate a registered pharmacist responsible for the oversight of the use of these devices. The responsibilities of this pharmacist are to ensure:

(1) Policies and procedures are in place for the safe use of patient medications that are removed from the devices, including those removed prior to pharmacist review of the prescriber's order.

(2) Conduct of quarterly audits of compliance with policies and procedures.

(3) Approval of the medication inventory to be stocked in the automated drug distribution devices.

(4) Supervision of medication preparation and distribution of medications used in automated drug distribution devices.

(5) That the stocking and checking of medications in the automated drug distribution devices is reserved to a pharmacist, pharmacy intern, or a pharmacy technician.

(a) Pharmacy technicians checking automated drug distribution devices must have completed competency-based training and have documentation of the training on file in the pharmacy.

(b) The board may approve electronic bar code checking, or other approved technology, in place of manual double-checking of the medications stocked in the automated drug distribution devices.

(6) Ensure the security of medications in automated drug distribution devices by:

(a) Limiting access to licensed health personnel consistent with the patient care services identified within their scope of practice;

(b) Controlling user access to prevent unauthorized access to the devices;

(c) Monitoring controlled substance usage and taking appropriate action as warranted; and

(d) Working in cooperation with nursing administration to maintain an ongoing discrepancy resolution and monitoring process.

(7) A process is in place for all staff using the automated drug distribution devices to receive adequate training.

(8) Pharmacist participation in the facility automated drug distribution devices system quality assurance and performance improvement program.

NEW SECTION

WAC 246-872-040 What are the responsibilities of the facility in the use of automated drug distribution devices? The licensed health care facility must maintain readily available policies and procedures for the use of automated drug distribution devices that

address:

(1) Type of equipment, components, and locations.

(2) Medication and information access.

(a) The automated drug distribution devices must have a system in place to record all medication removal or return including date and time, identity of user, patient name, complete description of medication, quantity, and cosignatures, if required;

(b) The record of medications filled, inventoried, or stocked including identification of the person accessing the automated drug distribution devices shall be readily retrievable and maintained by authorized personnel; and

(c) The records for patients discharged from the facility must be removed from the automated drug distribution devices data base within twelve hours.

(3) Medication refilling and removal.

(a) All medications in the automated drug distribution devices must be packaged and labeled in compliance with state and federal laws;

(b) All controlled substances activities must comply with requirements of state and federal laws;

(c) The process for securing and accounting for returned or wasted medication is defined; and

(d) Verification that a patient's information in automated drug distribution devices match facility records.

NEW SECTION

WAC 246-872-050 What are quality assurance and performance improvement requirements for the use of automated drug distribution devices? Each facility shall establish and maintain a quality assurance and performance program that includes but is not limited to:

(1) Accuracy of medication filling and removal;

(2) Regular review of controlled substances discrepancies;

(3) Use of the data collected to take action to insure quality of care and make improvements to the automated drug distribution device system;

(4) Documentation of the outcomes of the quality assurance activities.